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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,658	11/29/2001	James M. Coull	027232-000910US	5256

20350 7590 04/01/2009  
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EXAMINER
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SISSON, BRADLEY L

ART UNIT	PAPER NUMBER
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1634

MAIL DATE	DELIVERY MODE
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04/01/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/996,658	<b>Applicant(s)</b> COULL ET AL.	
	<b>Examiner</b> Bradley L. Sisson	<b>Art Unit</b> 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,4,5,7,8,11,15-18,21,22,24-26,29-31,35,38,39,41-43 and 46-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4,5,7,8,11,15-18,21,22,24-26,29-31,35,38,39,41-43 and 46-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 17 February 2009 has been entered.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1, 4, 5, 7, 8, 11, 15-18, 21, 22, 24-26, 29-31, 35, 38, 39, 41-43, and 46-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,110,676 (Coull et al.) in view of US Patent 5,612,458 (Hyldig-Nielsen et al.), and US Patent 5,225,584 (Brooks et al.) in view of applicant's admissions.

6. Coull et al., disclose and claim a method of determining the presence of a nucleic acid in a sample. As set forth on column 1, probe assays have been used to detect bacteria, fungi, virus-applicant's "microbes."

7. Coull et al., teach that the hybridization reaction comprises the use of peptide nucleic acid (PNA) probes that are detectable yet unlabeled. The aspect of using antibodies to detect the presence of PNA – target duplexes is disclosed.

8. Coull et al., makes reference to US Patent 5,612,458 (Hyldig-Nielsen et al.)

9. Hyldig-Nielsen et al., disclose the development and use of antibodies that bind specifically to PNA:DNA as well as PNA:RNA duplex structures, and how these antibodies can be used to detect the presence of target nucleic acids.

10. Hyldig-Nielsen et al., column 3, lines 30-33, teach that their antibodies “are useful in the capture, recognition, detection, identification or quantification of one or more chemical or biological entities.

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11. Hyldig-Nielsen et al., column 3, lines 41-43, teach that the antibodies may be detectably labeled.
12. Hyldig-Nielsen et al., column 6, lines 50-56, teach that the antibodies may be attached to any of a variety of detectable materials, including that which is chemiluminescent or fluorescent.
13. Hyldig-Nielsen et al., has not been found to further characterize the nature of form of these various detectable moieties.
14. Brooks et al., column 18, bridging to column 19, discloses the development and use of various chemiluminescent labels, and that these labels can be used in combination with immunoassays as well as nucleic acid hybridization assays. The applicability of the labels to the assays and their use with supports that can take the form of arrays as well as membranes, beads, microtiter plates, etc. is specifically disclosed.
15. Applicant, at page 3 of the specification, admits in the record that hybridization reactions using antibodies was known in the art. Applicant also admits that color-coded beads, which comprise fluorophores, are commercially available and that these beads are useful in “Molecular Biology, Immunoassays, Enzymatic Assays & Reporter-Ligand Assays.”
16. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Coull et al., which includes the use of antibodies that bind to the PNA-DNA or PNA:RNA complex, by use of a solid support such as those identified by Brooks and known in the art as disclosed by applicant, as such would have accorded the ordinary artisan with an efficient, sensitive, and reproducible method of detection. In view of the detailed teachings of the prior art of record, said ordinary artisan would have had a most reasonable expectation of success.

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Response to argument

17. At page 13, bridging to page 14, of the response submitted 17 February 2009, applicant asserts:

Coull et al., Hyldig-Nielsen et al., and Brooks et al., either alone or in combination, do **not** teach or suggest a method employing the selectivity and discriminating power of an antibody immobilized on a solid carrier (e.g., a coded bead), as used in a capture assay, in combination with the selectivity and discriminating power of a PNA molecular probe, as used to stain microbial organisms, to provide for two independent levels of certainty and/or discrimination. (Emphasis in the original.)

18. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., use of coded beads linked to antibodies) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

19. Assuming *arguendo*, that the claims were so limited, it is noted that the record comprises admissions by applicant that such beads were known in the art at the time of filing and that they were known to be useful for coupling to antibodies and being used in immunoassays.

20. Attention is directed to MPEP 2129, which states in part:

I. ADMISSIONS BY APPLICANT CONSTITUTE PRIOR ART

A statement by an applicant >in the specification or made< during prosecution identifying the work of another as "prior art" is an admission \*\*>which can be relied upon for both anticipation and obviousness determinations, regardless of whether the admitted prior art would otherwise qualify as prior art under the statutory categories of 35 U.S.C. 102. *Riverwood Int'l Corp. v. R.A. Jones & Co.*, 324 F.3d 1346, 1354, 66 USPQ2d 1331, 1337 (Fed. Cir. 2003); *Constant v. Advanced Micro-Devices Inc.*, 848 F.2d 1560, 1570, 7 USPQ2d 1057, 1063 (Fed. Cir. 1988).

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At page 13 of the response applicant also cites *KSR International Co. v. Teleflex Inc.* 82 USPQ2d 1385 (U.S. 2007). It is noted that *KSR* states in part:

When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.

21. It is further noted that prior art is not limited to the four corners of the documentary prior art being applied. Prior art includes both the specialized understanding of one of ordinary skill in the art, and the common understanding of the layman. It includes “background knowledge possessed by a person having ordinary skill in the art. . . [A] court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR* at 1396.

22. Suggestion, teaching or motivation does not have to be explicit and “may be found in any number of sources, including common knowledge, the prior art as a whole or the nature of the problem itself” *Pfizer, Inc. v. Apotex, Inc.* 480 F.3d 1348, 82 USPQ2d 1321 (Fed. Cir. 2007) citing *Dystar Textilfarben GMBH v. C. H. Patrick Co.*, 464 F.3d 1356 (Fed. Cir. 2006).

In the present case, both immunoassays and hybridization assays were well known in the art and had been practiced for decades. Further, the aspect of linking antibodies to any of a wide variety of substances, be they detectable or not, was well known. And applicant has admitted that it was known in the art to conduct combined hybridization and immunoassays, and that the linking of antibodies to coded beads, which comprise fluorescent molecules was also known. Clearly, the use of antibodies bound to a support constitutes one of the “identified, predictable solutions, a person of ordinary skill in the art” would know of and would have “good reason to pursue the

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known options within his or her technical grasp.” *KSR*. Indeed, there has be no showing that one of skill 9n the art would not have expected that antibodies, bound to a support, would not be expected to bind to an antigenic determinant. Accordingly, and in the absence of convincing evidence to the contrary, the rejection is maintained.

### ***Conclusion***

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

24. If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Ram Shukla, Ph.D. can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

25. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bradley L. Sisson/  
Primary Examiner, Art Unit 1634